

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

March 1, 2005
Fifth Floor
Conference Room 2

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

- CALL TO ORDER:** A meeting of the Board of Pharmacy was called to order at 9:10 a.m. Mr. Ross, Vice Chairman, called the meeting to order.
- PRESIDING:** Mark A. Oley, Chairman (arrived 9:13)
- MEMBERS PRESENT:** Gill B. Abernathy
Michael J. Ayotte
John O. Beckner
Willie Brown
Michelle R. Easton (arrived 9:30)
Bobby Ison
Leo H. Ross
- MEMBERS ABSENT:** Toni Aust
Kimberly A. Anderson
- STAFF PRESENT:** Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Ralph A. Orr, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst
Donna M. Lee, Administrative Assistant
- Howard M. Casway, Senior Assistant Attorney General, was not present.
- QUORUM:** With six members of the Board present, a quorum was established.
- Ms. Reiniers-Day read the emergency evacuation procedure for Conference Room 2.
- APPROVAL OF AGENDA:** The revised agenda was approved as presented.
- Mr. Ayotte moved, and the Board voted unanimously, to approve the agenda.
- PUBLIC COMMENTS:** No public comments were received at this time.
- APPROVAL OF MINUTES:** Mr. Oley called for changes or corrections to the minutes of December 10, 2004. Hearing no changes, the minutes were approved as presented.

**ADOPTION OF DRAFT
SANCTION WORKSHEET:**

Neal Kauder reviewed with the Board the process for utilizing the draft sanction worksheet as a tool to assist the Board in sanction determinations and requested that the Board adopt the draft sanction worksheet. He stated that the Board of Medicine is using the worksheet in all informal conferences and the respondent received a copy of the completed worksheet, but it is not available to the public.

Mr. Ayotte moved, and the Board voted unanimously, to adopt the sanction reference worksheet to be used as a trial voluntary basis at informal conferences held for a period of three months, and that the process would then be further reviewed by the Board after three months (Attachment 1). The Board also voted unanimously that if Board counsel recommends that the worksheet be distributed to respondents, that the Board would not go forward with the trial until the matter could be further considered at the next Board meeting held on June 7, 2005.

**MINUTES FROM BOARD
OF HEALTH
PROFESSIONS:**

Ms. Easton presented the minutes from January 12, 2005 Board of Health Professions meeting.

LEGISLATIVE UPDATE:

Ms. Yeatts reviewed with the Board a handout that outlined the legislative actions of the 2005 General Assembly as it related to legislation affecting the Board of Pharmacy.

**ADOPTION OF FINAL
RULES ON DELEGATION
TO AN AGENCY
SUBORDINATE:**

Ms. Yeatts informed the Board that adoption of the final rules on delegation to an agency subordinate would replace the emergency regulations that are in effect until July 15, 2005. She stated that no public comments were received.

Mr. Ross moved, and the Board voted unanimously, to adopt the final rules on delegation to an agency subordinate to replace the emergency regulations. (Attachment 2)

**CONSIDERED A CHANGE
TO PROPOSED
WHOLESALE
DISTRIBUTOR
REGULATIONS TO
ALLOW A LIMITED-USE
LICENSE FOR MEDICAL
GAS DISTRIBUTORS:**

Ms. Russell reviewed with the Board an addition to the proposed wholesale distributor regulations that were adopted by the Board on December 10, 2004. The addition would allow for a special or limited use license for medical gas distributors. Ms. Russell stated that this is necessary as most gas distributors do not need to comply with many of the regulations for wholesale distributors of other prescription drugs because there is little to no risk of counterfeiting. This change will assist the Board in determining who the full-service wholesale distributors are.

**CONSIDERED WHETHER
A NON-RESIDENT
PHARMACY
REGISTRATION SHOULD
BE ISSUED WHEN A
STATE INSPECTION
REPORT CANNOT BE
PROVIDED (54.1-3434.1 A
2)**

Mr. Beckner moved, and the Board voted unanimously, to adopt the proposed change to the wholesale distributor regulations to allow for special or limited-use licenses for medical gas distributors. (Attachment 3).

The Board was informed that § 54.1-3434.1 A 2 requires that a non-resident pharmacy applicant must submit a copy of the most recent inspection report from their state regulatory or licensing agency when they submit an application to the Board for licensure. Ms. Russell advised the Board that within the last year the Board office has received applications that are either without inspection reports because the applicant's state may not require an inspection before they receive a license, or in one case the most recent inspection was conducted over 12 years ago. Ms. Russell asked the Board for their guidance on whether a non-resident pharmacy license should be issued when there is not an inspection report.

Mr. Beckner moved, and the Board voted unanimously, that a guidance document should be drafted that defines the word "recent" to reflect a time period of three to five years for an inspection report, and to present the guidance document for approval at the next Board meeting on June 7th. The Board further recommended that an application submitted without an inspection report less than five years old should be denied until the applicant can supply a recent inspection report.

**REVIEWED THE IMPACT
OF ACPE'S RECENT
DECISION TO REMOVE
PHARMACEUTICAL
MANUFACTURERS AS
APPROVED CE
PROVIDERS:**

The Board reviewed the recent decision by ACPE to no longer recognize pharmaceutical manufacturers as accredited providers of continuing education as of July 1, 2005. The Board recommended that Board staff gather further information from ACPE about this change and present its findings to the Board at its June 7th meeting, and that a decision be deferred until then as to how the Board will communicate ACPE's decision to pharmacists throughout Virginia.

**COMMENT TO DEA ON
RECENT
INTERPRETATION OF
SCHEDULE II
PRESCRIBING:**

The Board was informed that in November 2004, DEA sent a letter to physicians stating that the practice of preparing multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills for a Schedule II controlled substance. Ms. Russell stated that the Board office, because of the recent DEA interpretation, has received numerous telephone calls from pharmacists inquiring as to whether or not they should fill a prescription. She further stated that the current practice is not a violation of state law and is not specifically prohibited by federal law. She also stated that DEA is accepting public comment on the recent decision.

Mr. Ayotte moved, and the Board voted unanimously, that the Executive Director submit written comment on behalf of the Board to DEA opposing the recent interpretation and asking that they rescind it, and return to the previous policy.

**REQUEST BY MHMRASA
FOR AMENDMENT TO
GUIDANCE DOCUMENT
110-18**

John Morgan addressed the Board regarding the request by Mental Health, Mental Retardation and Substance Abuse Services (MHMRASA) to amend Guidance Document 110-18 to permit physicians and registered nurses at Community Services Board to prepare in advance a pill box with up to a 14-day supply of medications for patients living in private residences who would normally self-administer the medications. Dr. Morgan explained to the Board that they are concerned about safety issues, particularly suicide risks, of sending a patient home with a 30-day supply of medications; therefore, they provide a 14-day supply for a patient in an unlabeled "pill-box", and maintain the prescription bottle with the label at the community services board clinic.

The Board expressed concern about how hospital and emergency personnel would know what type of medications the patient was using since there would not be a prescription label in the home. Mr. Morgan informed the Board that the facilities are open twenty-four hours a day, seven days a week, and could be contacted by hospital and emergency personnel. After discussion with the Board, Mr. Morgan agreed that placing a label on the pill box with a telephone number of the applicable CSB would be something that could reasonably be accomplished.

Mr. Ayotte moved, and the Board voted unanimously, to extend the interpretation of Guidance Document 110-18 to include physicians and nurses working at the community services board.

**EXECUTIVE DIRECTOR'S
REPORT:**

- **NABP ANNUAL
MEETING:**
- **REPORT ON THE
RENEWAL
PROCESS AND
SURVEY RESULTS:**
- **TECHNICIAN
EXAM AUDIT AND
STATISTICS**

The annual NABP meeting will be held in New Orleans on May 21-24, 2005. Mr. Oley and Ms. Russell will be attending. Mr. Brown, Mr. Ison and Mr. Ross indicated they would also like to attend if they are granted approval.

The Board reviewed data on the recent renewal process. The data showed that 7,045 pharmacists and 4,258 technicians renewed on line and completed the survey.

Ms. Russell also informed the Board that an independent audit report of the pharmacy technician examination was conducted by Dr. Dana Hammer from the University of Washington, and the

examination was determined to be in compliance with all 21 standards of the National Commission for Certifying Agencies and to be psychometrically sound. As of February 28, 2005, 3580 candidates have taken the exam. The average score is 78.4% and the percentage of candidates passing the examination during the last four months is 69.0%.

NEW BUSINESS:

Ms. Russell stated to the Board that Dr. McCance-Katz, Medical Director for HPIP, informed the Department that in the near future some current out-patient treatment programs will no longer be in existence, and this may impact respondents or licensees on probation seeking treatment for substance abuse.

CONSENT ORDER:

- **CLOSED SESSION:**

Mr. Ross moved, and the Board voted unanimously to enter into closed session pursuant to Section 2.2-3711(A)(28) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a consent order. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, and Donna Lee attend the closed session because their presence was deemed necessary and would aid the Board in its deliberations.

- **RECONVENE:**

Mr. Ross moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session.

Mr. Beckner moved, and the Board voted unanimously, to offer Daniel Lineberry a consent order for the revocation of his pharmacist license.

ADJOURN:

With all business concluded, the meeting adjourned at 11:40 a.m.

Elizabeth Scott Russell
Executive Director

Donna M. Lee
Administrative Assistant

Mark A. Oley, Board Chairman

Date

BOARD OF PHARMACY ■ SANCTION REFERENCE POINT WORKSHEET INSTRUCTIONS

Case Type

(score only one, see list page 5)

- A. Enter "50" if case involves an Inability to Safely Practice. These cases include:
- Incapacitation— mental/physical
 - Impairment— drugs/alcohol
 - Inability to Safely Practice— other
 - Drug Related—excessive dispensing
 - Drug Related— security
 - Drug Related— obtaining drugs by fraud
 - Drug Related— personal use
 - Drug Related— other
- B. Enter "35" if the case involves a Business Practice issue. These cases include:
- Criminal Activity
 - Business Practice Issues
 - Fraud
 - Unlicensed Activity
 - Records/Inspections/Audits
- C. Enter "10" if the case involves a Prescription Error. These cases include:
- Strength/Quantity
 - Directions/Expired Medications
 - Wrong Drug
 - Wrong Patient/Physician Name
 - Generic/Brand

Offense Factor Scoring

(score all that apply)

- A. Enter "70" in cases where an individual may have committed an act or is highly likely to commit an act that constitutes significant and substantial danger to the health and safety of any person (Priority A) or in cases where an individual may have committed a harmful act to another person but does not pose an imminent threat to public safety (Priority B).

- B. Enter "50" if there was financial or other material gain from the offense.
- C. Enter "50" if there was an act of commission. An act of "commission" is interpreted as purposeful, intentional, or clearly not accidental.
- D. Enter "50" if the respondent was impaired at the time of the incident. Impairment can include drugs, alcohol, mental and/or physical.
- E. Enter "10" if the patient was injured. Patient injury includes any injury reported by the consumer regardless of follow up treatment.

Prior History Scoring

(score all that apply)

- A. Enter "30" if the respondent has had any past difficulties or treatment in any of the following areas: drugs, alcohol, mental health and/or physical health. Difficulties in these areas must be relevant to the current case and treatment must have been provided by a bona fide health care practitioner.
- B. Enter "10" if the respondent has had one or more prior Board violation.
- C. Enter "10" if the respondent has had a prior violation similar to the current case. Cases are considered similar when they fall within the same category.

Inability to Safely Practice

- Incapacitation— mental/physical
- Impairment— drugs/alcohol
- Inability to Safely Practice— other
- Drug Related— excessive dispensing
- Drug Related— security

- Drug Related— obtaining drugs by fraud
- Drug Related— personal use
- Drug Related— other

Business Practice

- Criminal Activity
- Business Practice Issues
- Fraud
- Unlicensed Activity
- Records/Inspections/Audits

Prescription Error

- Strength/Quantity
- Directions/Expired Medications
- Wrong Drug
- Wrong Patient/Physician Name
- Generic/Brand

Total Score

Sum all points on the worksheet and locate the sanction recommendation on the threshold table provided.

Scoring Outcome

The use of the Sanction Reference Points is voluntary. In addition, the worksheet sanction result may be combined with sanctions from lower sanction thresholds. For example, should a respondent fall within the "Reprimand/Monetary" area with a score of 40, the Board may choose a sanction package that includes a "Monetary Penalty" and a "Knowledge Based" sanction.

BOARD OF PHARMACY ■ SANCTION REFERENCE POINT WORKSHEET

■ Case Type (score one) **Points** **Score**

Inability to Safely Practice 50
Business Practice 35
Prescription Error 10

■ Offense Factors (score all that apply) **Points** **Score**

Priority A or B 70
Financial/material gain 50
Act of commission 50
Respondent impaired during incident 50
Patient injured 10

■ Prior History (score all that apply) **Points** **Score**

Any past substance abuse or treatment 30
One or more prior Board violations 10
Any prior similar Board violations 10

Total Respondent Score

THRESHOLDS

Knowledge Based 0-30
Reprimand/Monetary 31-120
Monitoring/Treatment/Refer to Formal 121+

■ Respondent: _____

License Number: _____

Virginia Board of Pharmacy

Final Regulations for Delegation of Informal Fact-Finding to an Agency Subordinate

*Replacing emergency regulations in effect: July 15, 2004 to July 14, 2005
(Public comment from 12/13/04 to 2/11/05)*

18VAC110-20-15. Criteria for delegation of informal fact-finding proceedings to an agency subordinate.

A. Decision to delegate.

In accordance with § 54.1-2400 (10) of the Code of Virginia, the board may delegate an informal fact-finding proceeding to an agency subordinate upon determination that probable cause exists that a practitioner may be subject to a disciplinary action.

B. Criteria for delegation. Cases that may not be delegated to an agency subordinate, except as may be approved by a committee of the board, include those that involve:

1. Intentional or negligent conduct that causes or is likely to cause injury to a patient;

2. Drug diversion;

3. Impairment with an inability to practice with skill and safety;

4. Indiscriminate dispensing;

5. Medication error in administration or dispensing.

C. Criteria for an agency subordinate.

1. An agency subordinate authorized by the board to conduct an informal fact-finding proceeding may include board members and professional staff or other persons deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals.

2. The executive director shall maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated.

3. The board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.

18VAC110-50-60. Special or limited-use licenses.

The board may issue a limited-use wholesale distributor license to entities that do not engage in the wholesale distribution of prescription drugs except medical gases and may waive certain requirements of regulation based on the limited nature of such distribution.